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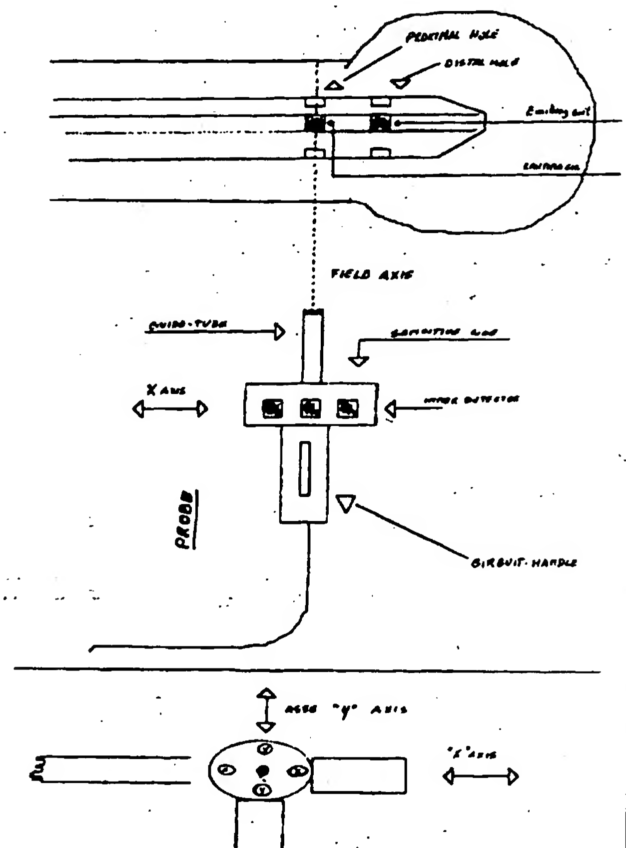
(54) Title: PROBE FOR LOCATING HOLES IN ORTHOPAEDIC INTERNAL FIXATION DEVICES

(57) Abstract

The necessity of the use, sometimes excessive, of an image intensifier in order to localize the holes for the screws in the internal fixation procedure with an interlocking nail implies an increase of the risks of radiation exposure involving the orthopaedic surgeon, the operation theatre personnel and the patient. The use is proposed of a magneto-resisting probe which looks for a signal produced by 2 microelectromagnets fixed to a rod which is introduced along the intramedullary nail: a high frequency alternating signal is produced by the two microelectromagnets and is recorded by the probe on the skin. The probe is made of 4 magneto-resistive sensors arranged on orthogonal axes for a more precise and straightforward location in the x and y directions. A screen with 4 arrows shows the direction one should follow for correct centering over the holes. A fourth possibility is represented by a small neodymium magnet, which can be inserted as a plug in the nail hole or fixed to a rod inserted into the canal of the nail, allowing a quick and precise localization of the hole and reducing the exposition time to radiation as well as the overall surgical procedure duration.



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1 TITLE

PROBE FOR LOCATING HOLES IN ORTHOPAEDIC INTERNAL FIXATION DEVICES

TECHNICAL FIELD

2 Many different techniques are employed in current orthopaedic and traumatologic
practice according to the bone segment involved and to special surgical indications.
In long bone fractures the use of intramedullary metallic means, static, dynamic or
mixed (Grosse Kempf, Kuntscher, A.O., etc.), control segmental rotation and
mantain the desired limb length. The great advantage of intramedullary fixation is
3 demonstrated by the simple technique, by the reducet extension of the skin incision
for the nail insertion and by the prevention of fracture site opening. Nevertheless
such procedure requires repeated x-ray controls, or image intensifier shots, with
exposure of the patient and the O.R. personnel to ionizing radiations.

BACKGROUND ART

4 These controls are necessary to guide the nail into the medullary canal of the
second fracture segment and subsequently to fix the screws which interlock the nail
and neutralize the rotation forces keeping the limb lenght. Despite the validity of
the different centering gauges, the amplioscope is frequently and excessively used
to recognize the nail holes, mainly the distal ones, and to fit the corresponding
5 screws in, increasing in this way the radiological risks.
The enthusiasm for this fixation tecnhique due to its semplicity and undeniable
validity has been cooled down by the excessive repeated exposure of the
orthopaedic surgeon to ionizing radiations.
The proposed solutions to accomplish this operation, although functional and
6 simple "in vitro", have showed their limits "in vivo" where the reduction of
radiological exams in order to center the interlocking screw into the corresponding
hole was not satisfactory.
Many orthopaedic surgeons have therefore aimed their interest to other fixation
systems, less valid and with a more limited indication range, but which did not
7 demand a frequent use of radiological pictures.

DISCLOSURE OF INVENTION

The recognition of the hole of the intramedullary nail and the subsequent aiming of a screw is possible by a simple and harmless device which uses an electromagnetic probe that localizes metallic means and reveals the holes with on-off mechanism.

The probe is made by an inductive sensor of proximity which an internal high frequency oscillator that produces an elecromagnetic field in the immediate vicinity of the sensor. The presence of a metallic object (actioner) in the action field of the sensor reduces the wideness of the oscillation since part of the electromagnetic energy is transferred from the sensor to the actioner on which dissipates for the effect of the parasitic currents of Focault. The wideness of the oscillation then decreases with the distance between actioner and sensor and may bring analogic information on the position of the object at the exit of the sensor or may be converted into a digital signal on-off by means of a Schmitt trigger. An electric circuit transforms this message into an acoustic and/or light (led) signal. In the presence of a metallic intramedullary nail the probe sensitizes and shows the presence with the acoustic and/or light signal. When the probe passes above the hole the signal stops. A microprocessor device converts this on/off signals on a monitor which allows a real time identification of the object and its configuration (hole: off).

The probe consists of a head (site of the electromagnetic device) and a handle which is guided by the operator sliding along the limb where a nail is present. The overall length is 15-20 cm. The head has a circular configuration and delimits a central hole; while sliding along the limb indicates the presence of the metallic object; at the level of the nail hole the signal fades till a complete interruption once the probe hole overlaps the nail hole. The skin point where the probe hole lies is the exact point where the incision may be made to drive correctly the interlocking screw.

Alternatively, one can use an electromagnetic probe with a sensor (sensor of Hall) which reveals the electromagnetic field produced by a small magnet. This small magnet is inserted in the hole of the nail inside a small pull-out screw (of metal or teflon). The probe contains a stabilized feeder, an hall-effect sensor, a differential amplifier, a Schmitt trigger, a low power transistor with open collector. In resting condition the base of the final transistor is not polarized therefore that transitor does not conduce. If, on the other hand, one approaches the south pole of a magnet to the body of the sensor, or the north pole to the opposite site, automatically one stimulates the Hall-effect sensor which on its turn generates a weak tension with an intensity proportional to the one of the applied magnetic field. This tension, amplified by the "differential", is applied at the entrace of the Schmitt trigger and, as soon as its value overtakes the threshold level of that trigger, the latter will produce a positive tension upon the base of the final transistor and will bring it into conduction.

As third possibility, one can use a magneto-resistive sensor made of special "bridge" resistances with a component sensitive to variations of the magnetic field which crosses them, in order to change the inner conductivity according to such field. Having a bridge connection and feeding them with a continous tension on two opposite sides the bridge, one can obtain a variation of the differential tension

on the other two sides proportional to the variation of the crossed magnetic field. The magnet which stimulates probe is characterized by a tiny cylindrical magnet of few millimeters, able to produce a magnetic field axial to the intramedullary nail
17 hole. It is inserted in the heas of a screw or a rod (metallic, teflon, PVC or other material) which temporality plugs the nail hole. Once the tiny magnet is applied to the nail the magneto-resistive probe records the magnetic field wich corresponds to the hole.

A fourth possibility is represented by the electromagnetic signal produced by 2
18 microelectromagnets fixed to the rod which is introduced along the intramedullary nail: a high frequency signal, betwenn 20 Khz and 1 Mhz, is produced alternatively by the two microelectromagnets and is recorded by the probe on the skin. The probe is made of 4 magneto-resistive sensor in crossed position for a more precise and straightforward research in the north, south, west and east directions. A
19 shielded wire brings the message to an electric circuit set at the desired distance which transforms this message into an acoustic or light signal. An alphanumeric system allows to quantify the distance. A screen with 4 arrows (above, below, right and left) shows the direction one should follow a correct centering. A special device connected to the probe enables the sensitivity selfcorrection: it is not
20 necessary therefore to manually correct the powermeter and one can limit the research to few essential gestures. The probe is contained in a small sterilisable cylider with the shape of a pen, a few millimeters of diameter, and allows the longitudinal gliding along the limb which hosts the nail. It is introduced in a specific guide which, once the hole has been localized, allow the extracion of the probe and
21 the introduction of the drill which pierces the bon without losing the precise alignment with the hole.

The screw containing the small magnet that plugs the nail hole will then be extracted with a screwdriver, the whole rod containing the magnet will be directly pulled out or a metallic rod will be used to catch the magnet.

22 BRIEF DESCRIPTION OF DRAWINGS

Fig. 1. Elecromagnetic probe Iron S3

Fig. 2. Electromagnetic probe for the recognition of metallic bodies and the discrimination of their holes durin special internal fixation techniques Orthopaedics.

23 Fig. 3. Two microelectromagnets emitting coils in a metallic or teflon rod (with preprinted circuit) in the medullary nail.

Fig. 4, 5, 6. Intramedullary metallic means in long bone fractures. The coil emitts an electromagnetic field with the main magnetic axis corresponding to the hole axis. Blocking system of the rod.

24 Fig. 7. In long bone fractures the use of intramedullary metallic means. The head has a circular configuration and delimits a central hole. The 4 (8) magnetic sensor have their sensitive surfaces a plane at 90° to the tube axis. The guide-tube allows the way through of the drill for the bone hole without losing the correct adjustment against the cortical bone, thanks to the special conformation of the head.

25 Fig 8. Monitor. On the graphic display unit the corresponding cartesian references are visualized.

Fig. 9. Iron S3. Generator - blocks.

Fig. 10. Circuit.

Fig. 11. Probe..

26 BEST MODE FOR CARRYNG OUT THE INVENTION

A current generator at 20 Khz sinusoidal frequency, with a rough 200 mA RMS intensity, is alternatively connected to 2 emitting coils in a mettalic or teflon rod (with preprinted circuit) in the medullary nail. The coil emitts an electromagnetic field with the main magnetic axis corresponding to the hole axis.

27 The detecting probe is formed by a teflon handle which supports an holed cylinder, containing 4 coils, each on a magnetic iron "semiolla", with the open side looking toward the head of the probe. The metallic guide-tube is inserted in the cylinder hole with the faceted and pointed extremity for the adjustment against the cortical bone.

28 The 4 magnetic iron sensor have their sensitive surfaces on a plane at 90° to the tube axis, with at the final phase of the research coincides whith the one of the searched magnetic field.

The positions on the plane are simmetric and equidistant (crosswise). When the probe is on the searched axis the signals induced by the field itself are equidistant
29 from the axis and therefore have equivalent intensity.

Such signal are conditioned, filtered and amplified in tension and current by a superficially mounted circuit inserted into the probe handle. The 4 amplified signal are transmitted by the connection cable to the instrumend containig the generator where they are received, refiltered and reamplified. Each signal is then revealed in
30 wideness by a dedicated circuit and transformed into continous current by a trimmer of final amplification adjustment.

The signal in continuos current, with a tension equivalent to the wideness of the corresponding in alternating current, are measured by a microcomputer containig a digital analogic converter.

31 The obtained measurements are again filtered at software level, visualized on a graphic and alphanumeric display unit. It is then obtained the difference of numeric values of each signal couple, relative to a diagonal of the cross. The ones relative to the diagonal parallel to the medullary rod form the X axis; those at 90° form the Y axis.

32 On the graphic display unit the corresponding cartesian references are visualized. If
the sum of the 4 monitored signals overtakes a minimal predefinite value a light
indicator on the cartesian plane is displayed, in order to obtain the indicator in the
center when the 4 signal are equivalent, or on the relative axis of the single couples
with Delta=0.
33 The guide-tube allows the way through of the drill for the bone hole without losing
the correct adjustment against the cortical bone, thanks to the special conformation
of the head. A metallic sheath, removable from the guide-tube, allows the insertion
of the scew (wose head has a wider diameter than the body) without removing the
handle of the probe from its leaning point against the cortical bone (corresponding
34 to the hole of the nail).
It is possible to obtain a threedimensional image by setting the Z axis too
(ortogonal to X and Y axes), determining absolute certain concidence of the hole
with the magnetic field, displayed on the screen by 2 coincident light signals.
Such axis (Z) is obtained joining the cylinder containing the 4 magnetic iron sensor
35 at 90° with another cylider with 4 sensor at 90° but with a 45° rotation in relation
to the first ones. The double evalutation allow the measurement of the magnetic
field variations even on a sagital plane, defining therefore the precise point (the
only one) of coincidence between the hole and the signal.
The research of the metallic object and the localization of the hole in the internal
36 fixation procedure with an intramedullary nail accomplished in this way largely
reduces the use of radiological appliances with all the risks connected with the x-
ray exposure ("stocastic" effects: genetic, leukemogenetic and oncogenetic
damages directly correlated to the absorbed dose). The system also reduces the
operation time, allowing the identification and the centering of nail hole
37 simultaneously.

RIVENDICATIONS

1. Use of the electromagnetic probe for the localization of metallic bodies in the
organism.

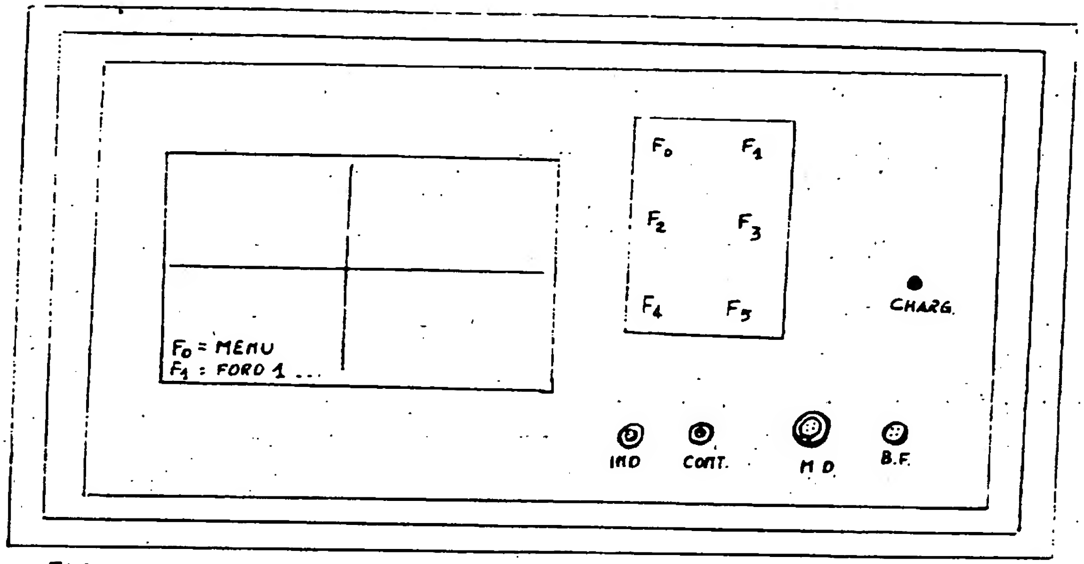
2. Device able to invert the perception of the electromagnetic signal and to localize
38 the hole (absence of metal) in metallic means used for osteosynthesis in
Orthopaedics.

3. Use of a small magnet inserted into the hole (directly or by means of a rod) to
enhance the precision of the hole localization by the electromagnetic probe.

4. Use of microelectromagnets able to sends a high frequency modulatable
39 electromagnetic signal, fixed to a rod sliding along the cavity of the fixation
system, and which overlap the intramedullary nail hole; the signal is caught by the
probe made of 4 magnetoresistive sensors, at crossways to increase precision.

5. Metallic (or teflon with preprinted circuit) rod containing 2 emitting coils,
connected to a current generator at definitite frequency and intesity, coincident
40 whith the holes, at definitive distance, to be introduced into the medullary rod.

6. Magnetic device according to the preceding rivendications featured by the fact
that it has been realised for the purposes and the uses above specified according to
what has been described and illustrated.



F_0 F_1
F_2 F_3
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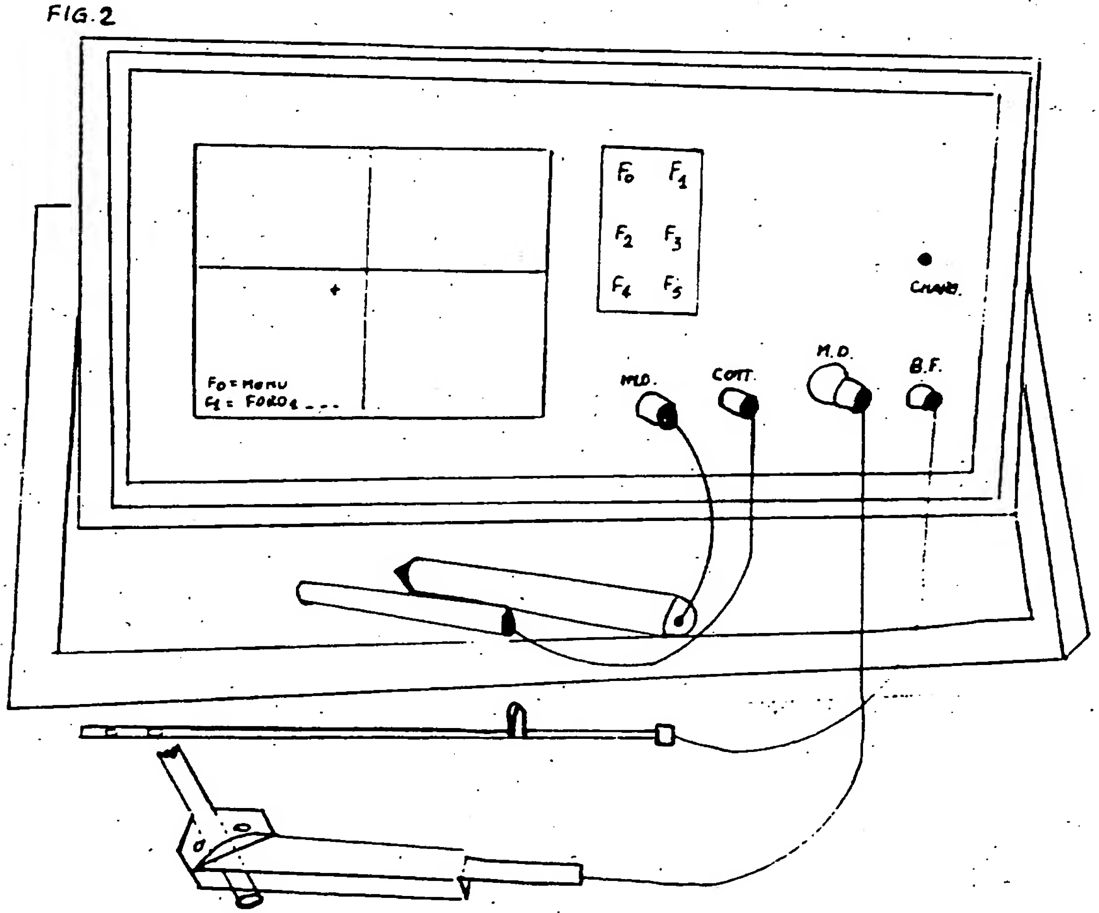
FIG. 1

FIG. 2



F_0 F_1
F_2 F_3
F_4 F_5
F_0 = MENU
F_1 = FORO 1 ...
IND.
CONT.
M.D.
B.F.

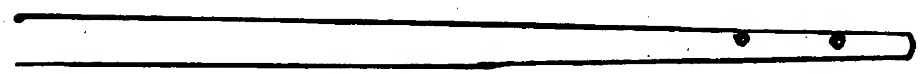
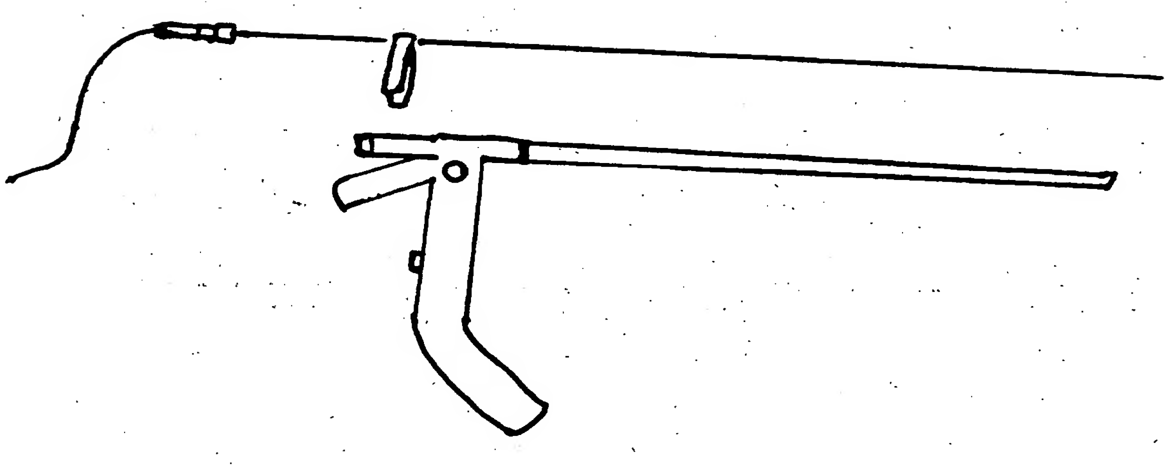


FIG.3

FIG.4



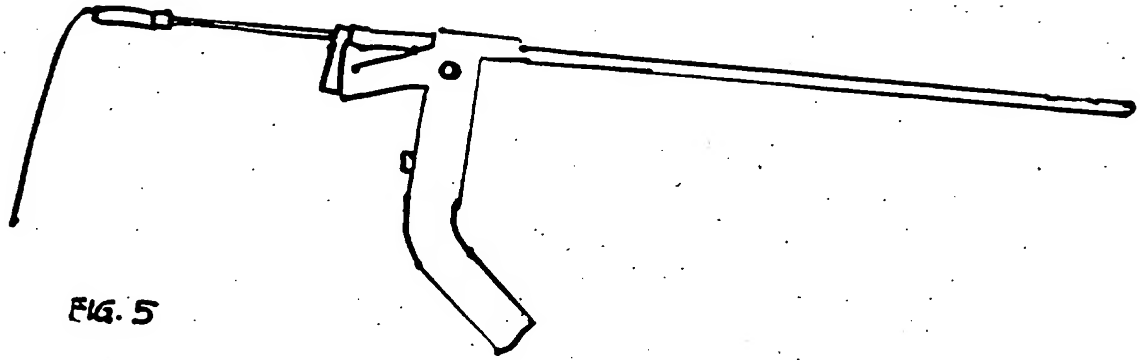
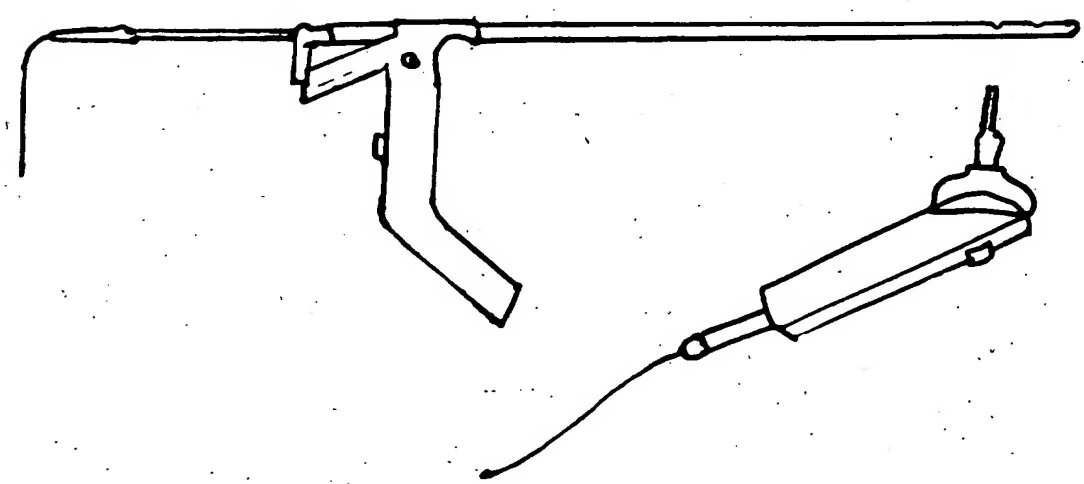


FIG. 5

FIG. 6



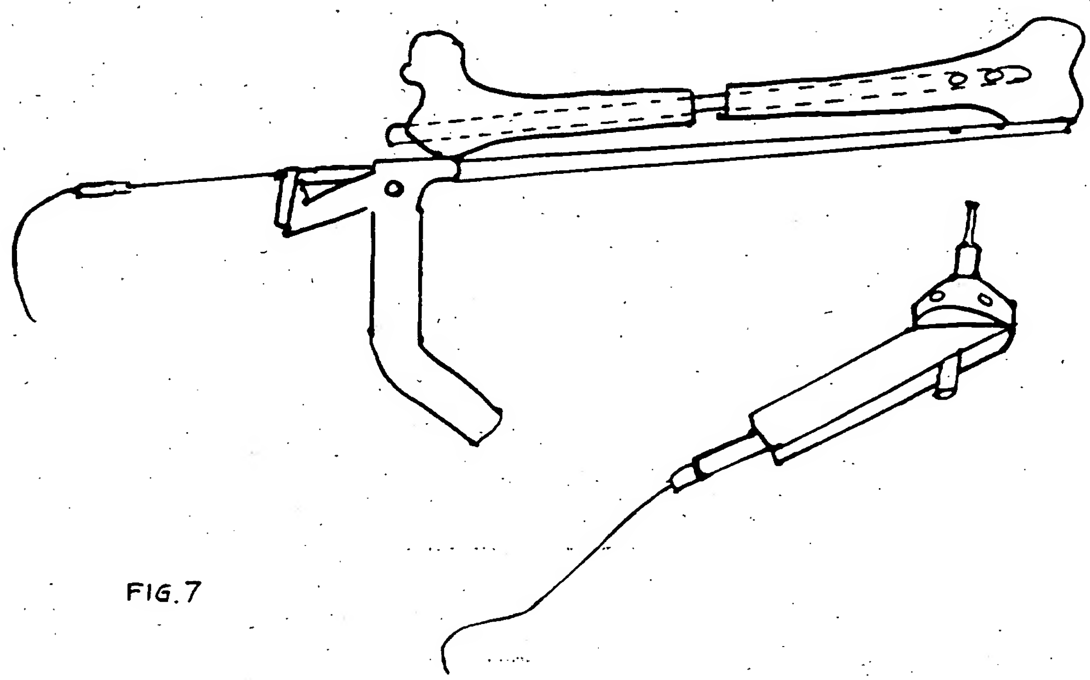
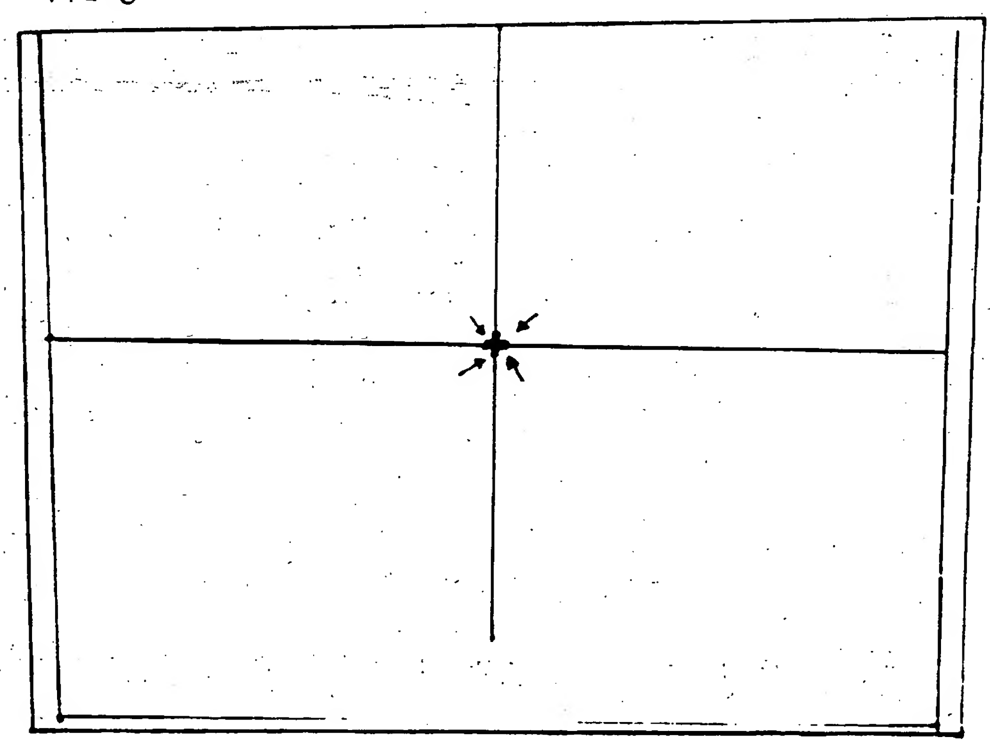
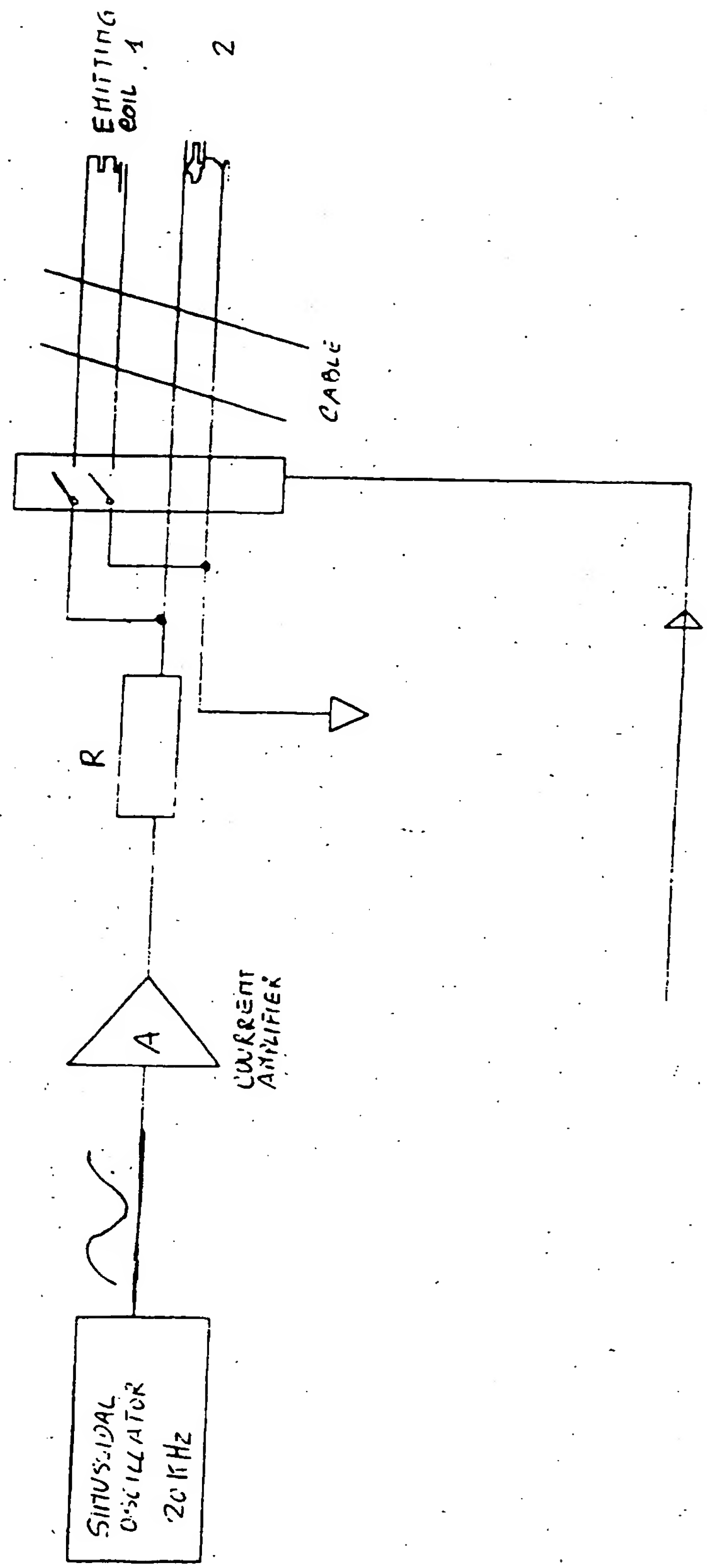


FIG. 7

FIG. 8

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2
CABLE
R
A
CURRENT AMPLIFIER
SINUSOIDAL OSCILLATOR 20 KHz

FIG. 9

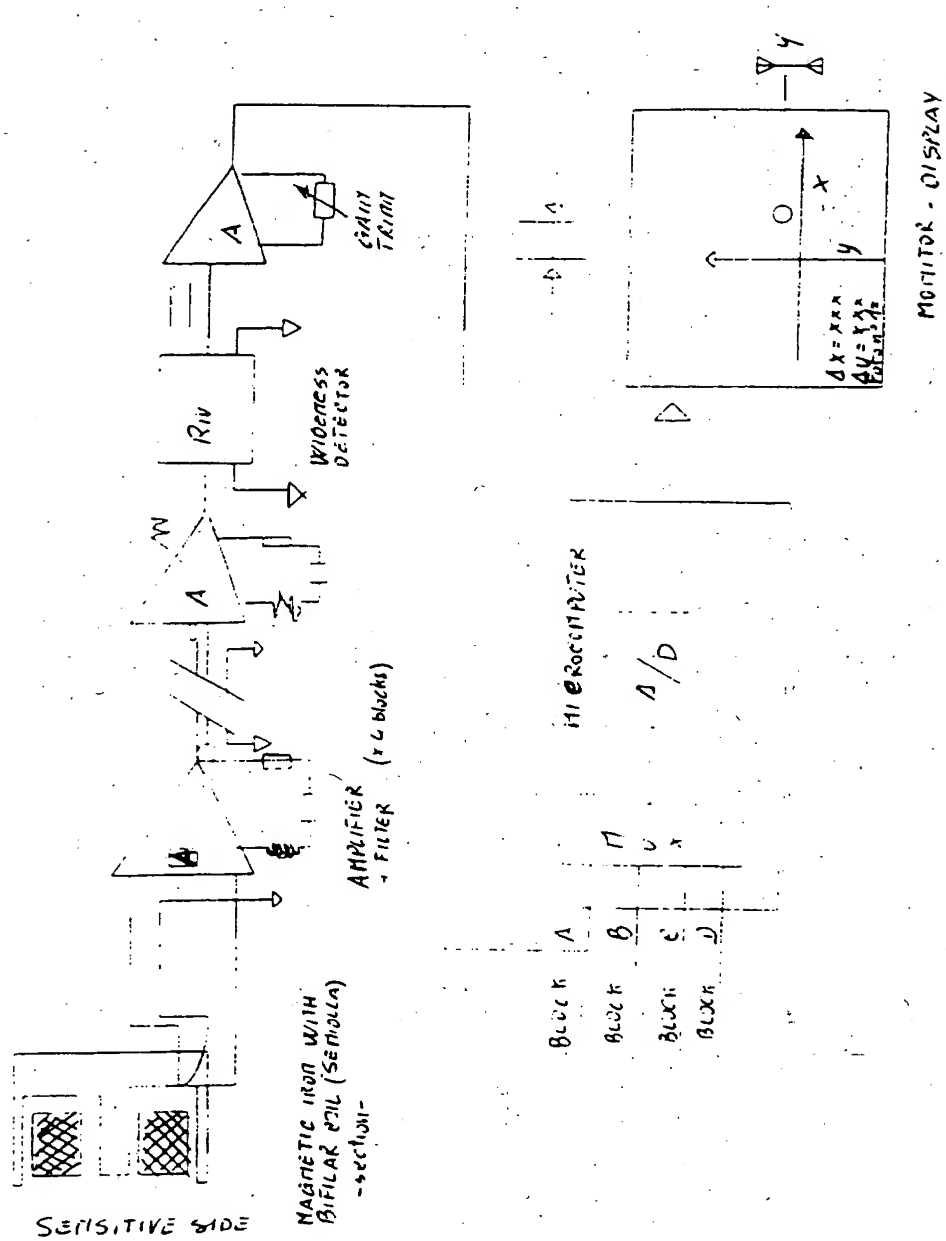
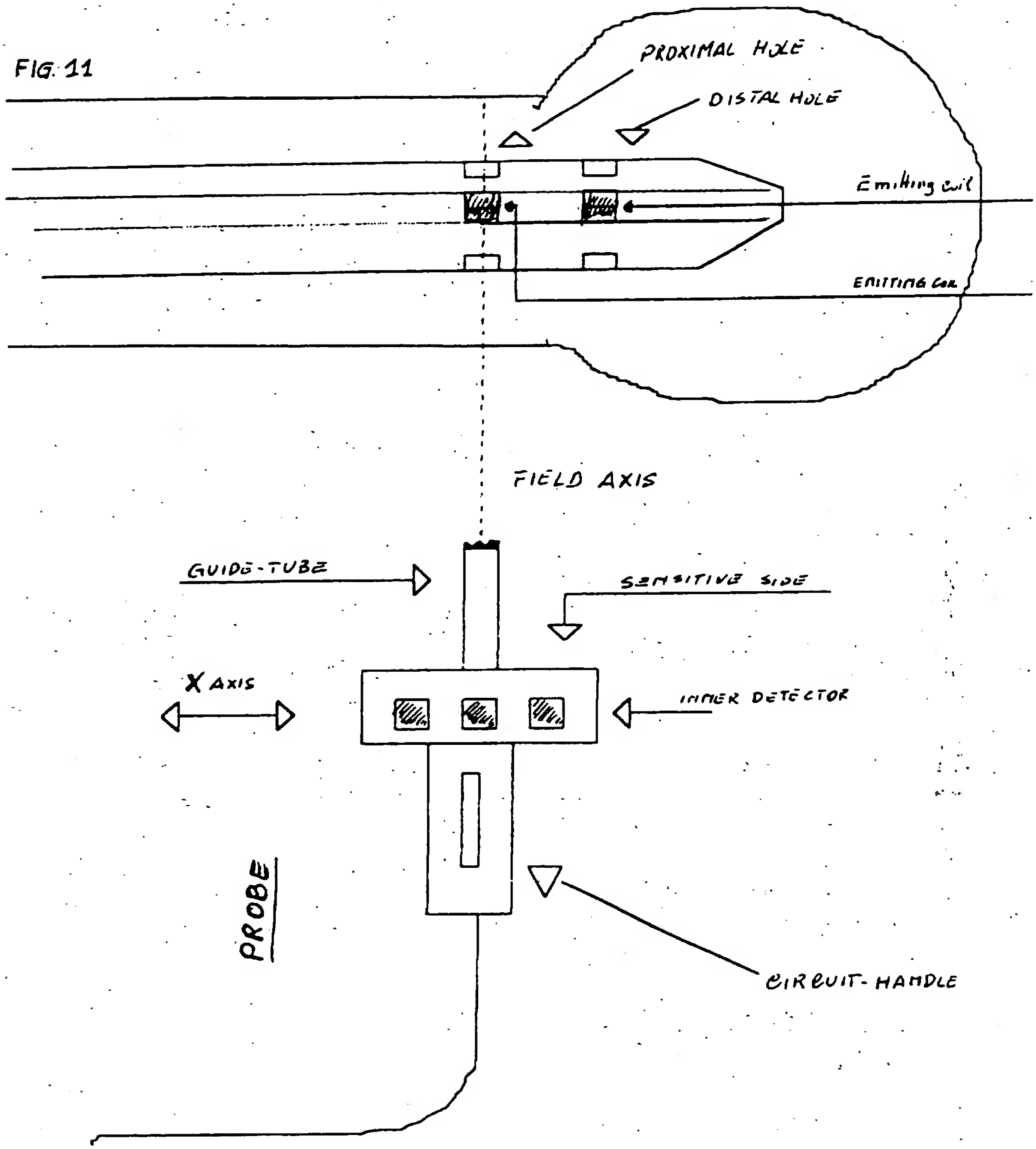

SENSITIVE SIDE
AMPLIFIER + FILTER
WIDENESS DETECTOR
GAIN TRIM
A/D
MONITOR - DISPLAY

FIG.10

FIG. 11


PROXIMAL HOLE
DISTAL HOLE
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EMITTING COIL
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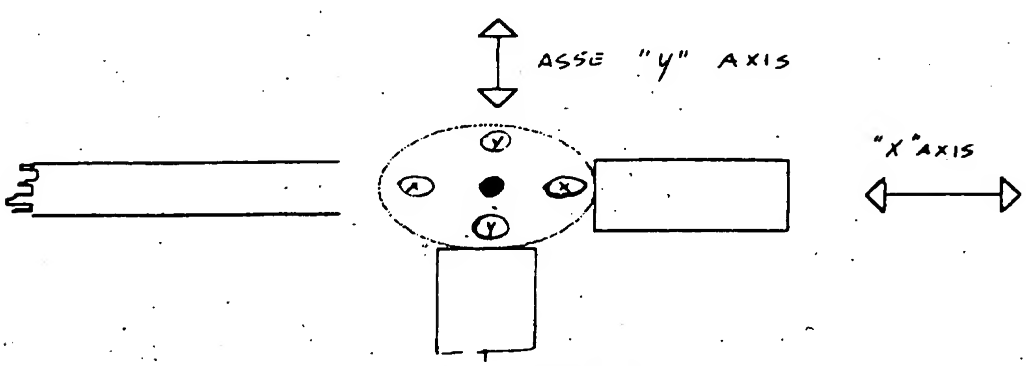
GUIDE-TUBE
SENSITIVE SIDE
X AXIS
INNER DETECTOR
PROBE
CIRCUIT-HANDLE


ASSE "Y" AXIS
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INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/17

According to International Patent Classification (IPC) or to both national classification and IPC

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IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 097 401 A (CENTRE D'ETUDE DE L'ENERGIE NUCLEAIRE) 4 January 1984 see abstract see page 2, line 23 - line 35 ---	1,6
X	EP 0 589 592 A (ORTHOFIX) 30 March 1994 see abstract ---	1,6
X	EP 0 628 287 A (M.L.VALSECCHI) 14 December 1994 see abstract; figure 2 ---	3,6
X	WO 95 00085 A (S.B.HOLLSTIEN ET AL.) 5 January 1995 see abstract; figure 1 see page 12, line 14 - line 17 ---	3-6
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1

Date of the actual completion of the international search	Date of mailing of the international search report
11 February 1997	19. 02. 97

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X	EP 0 523 905 A (STRYKER) 20 January 1993 see abstract; figures 1,2 see column 5, line 52 - column 6, line 13 see column 7, line 2 - line 19 ---	3-6
P,X	DATABASE WPI Section PQ, Week 9625 Derwent Publications Ltd., London, GB; Class P31, AN 96-250140 XP002024975 & RU 2 046 377 C (Y.Y.REUTOV ET AL.) , 20 October 1995 see abstract -----	1

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INTERNATIONAL SEARCH REPORT

Inter nal Application No
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		IT-B- 1262776	04-07-96
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